Supreme Court, U.S.
FILED
APR 13 2010
CLERK

No. 09-1022

IN THE

Supreme Court of the United States

BAYER SCHERING PHARMA AG AND
BAYER HEALTHCARE PHARMACEUTICALS INC.,
Petitioners,

v.

BARR LABORATORIES, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF OF PETITIONER

PETER B. BENSINGER, JR.
ADAM K. MORTARA
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 W. Hubbard Street
Suite 300
Chicago, IL 60654
(312) 494-4400

CARTER G. PHILLIPS*
JEFFREY P. KUSHAN
JONATHAN F. COHN
MATTHEW D. KRUEGER
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
cphillips@sidley.com

Counsel for Petitioners

* Counsel of Record

April 13, 2010

WILSON-EPES PRINTING CO., INC – (202) 789-0096 – WASHINGTON, D.C. 20002

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
REPLY BRIEF	1
I. THE FEDERAL CIRCUIT'S STANDARD CONFLICTS WITH SECTION 103, THIS COURT'S PRECEDENTS, AND THE DECISIONS OF EVERY OTHER CIRCUIT TO HAVE ADDRESSED THE ISSUE	1
II. BARR'S ARGUMENTS AGAINST CERTIORARI LACK MERIT	7
III. THE QUESTION PRESENTED HAS ENORMOUS CONSEQUENCES FOR A BROAD RANGE OF INDUSTRIES	10
CONCLUSION	12

TABLE OF AUTHORITIES

CASES — Page

Altoona Publix Theatres, Inc. v. *Am. Tri-ergon Corp.*, 294 U.S. 477 (1935) 1
Amgen Inc. v. *F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009) 2, 5, 6
Bell Atl. Corp. v. *Twombly*, 550 U.S. 544 (2007) 3
City of Erie v. *Pap's A.M.*, 529 U.S. 277 (2000) 4
Dow Chem. Co. v. *Halliburton Oil Well Cementing Co.*, 324 U.S. 320 (1945) 1
eBay Inc. v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006) 4
Ecolab, Inc. v. *FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009) 6
Eibel Process Co. v. *Minn. & Ontario Paper Co.*, 261 U.S. 45 (1923) 2
Graham v. *John Deere Co.*, 383 U.S. 1 (1966) 2
In re Kubin, 561 F.3d 1351 (Fed. Cir. 2009) 5, 11
KSR Int'l Co. v. *Teleflex Inc.*, 550 U.S. 398 (2007) 2, 5
Nixon v. *Fitzgerald*, 457 U.S 731 (1982) 10
In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988) 2
Pfizer, Inc. v. *Apotex, Inc.*, 488 F.3d 1377 (Fed. Cir. 2007) 6
Pharmastem Therapeutics, Inc. v. *Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) 5
Phillips v. *Detroit*, 111 U.S. 604 (1884) 1
Textile Mach. Works v. *Louis Hirsch Textile Machs., Inc.*, 302 U.S. 490 (1938) 1

United States v. *Williams*, 504 U.S. 36 (1992) 10
Verlander v. *Garner*, 348 F.3d 1359 (Fed. Cir. 2003) 5, 9

OTHER AUTHORITY

Webster's New Collegiate Dictionary (2d ed. 1951) 2

REPLY BRIEF

For 150 years, this Court has held that an invention is obvious only if it was "plainly foreshadowed," "plainly indicated," "perfectly plain," or "predictable." Barr does not dispute this. Nor does it dispute that, in the Federal Circuit, a patent can be invalidated as obvious when the inventor had only a "reasonable expectation" of success and further experimentation remained necessary to determine whether any of the "viable options" would succeed. Because the Federal Circuit's watered-down standard cannot be squared with this Court's precedents or section 103(a) of the Patent Act, and because it threatens to undermine patent rights and the incentives necessary to ensure continuing research and development of new advances in health care, certiorari is warranted. None of Barr's arguments to the contrary has any merit.

I. THE FEDERAL CIRCUIT'S STANDARD CONFLICTS WITH SECTION 103, THIS COURT'S PRECEDENTS, AND THE DECISIONS OF EVERY OTHER CIRCUIT TO HAVE ADDRESSED THE ISSUE.

1. The proper test is clear. This Court has consistently described the patentability standard with terms like "plainly foreshadowed," "plainly indicated," or "perfectly plain." *E.g.*, *Textile Mach. Works* v. *Louis Hirsch Textile Machs., Inc.*, 302 U.S. 490, 498 (1938); *Altoona Publix Theatres, Inc.* v. *Am. Tri-ergon Corp.*, 294 U.S. 477, 486 (1935); *Dow Chem. Co.* v. *Halliburton Oil Well Cementing Co.*, 324 U.S. 320, 327 (1945); see also, *e.g.*, *Phillips* v. *Detroit*, 111 U.S. 604, 608 (1884) (invalidating patent when claimed solution would have "naturally and spontaneously occur[ed] to any skilled mechanic").

And, in codifying this case law, Congress chose the term "obvious," meaning "[e]asily discovered, seen, or understood; plain; evident." *Webster's New Collegiate Dictionary* 581 (2d ed. 1951); see also *Graham* v. *John Deere Co.*, 383 U.S. 1, 14-15 (1966) (describing Congress's codification).

Under this standard, a claimed innovation is patentable if its success could not have been anticipated without "actual experiment[ation]." *E.g.*, *Eibel Process Co.* v. *Minn. & Ontario Paper Co.*, 261 U.S. 45, 62 (1923); see Pet. 14-15. If additional testing is required before success can be predicted, an invention is not "obvious." *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 421 (2007).

2. The Federal Circuit unquestionably did not apply this test—not in the decision below and not in most of its other decisions over the past three decades, both before and after *KSR*. Instead, in the Federal Circuit, a claimed invention is obvious if a person of ordinary skill would have had a "'reasonable expectation of success.'" Pet. App. 14a; see, *e.g.*, *Amgen Inc.* v. *F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1362 (Fed. Cir. 2009); *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988). As this case demonstrates, a "reasonable expectation of success" is markedly different from the standard Congress adopted and this Court has implemented. The panel majority found that a "'reasonable expectation of success'" existed because the invention appeared as a mere "viable option" and the inventor stood at a "crossroads," considering multiple options, all of which had "drawbacks," Pet. App. 12a-15a, and all of which required actual experimentation, *id.* at 14a-15a; see *id.* at 112a (finding that "to determine [the] effectiveness" of micronized, uncoated drospirenone,

clinical testing remained "necessary," through 1998) (emphasis added).

This Court has never applied a "reasonable expectations" test or anything remotely close to it. Barr asserts "[t]his is the standard set by *KSR*," Opp. 2, 7, but that is simply false. The words "reasonable expectation" nowhere appear in *KSR* or, for that matter, in any of this Court's other obviousness cases, which instead use terms like "perfectly plain" and "plainly indicated" to describe the proper analysis under § 103.

Nonetheless, Barr insists that, despite the stark differences in the formulations used by this Court and the Federal Circuit, the two standards are somehow one and the same. Opp. 15-16. How this could be so, Barr never explains, and in ordinary parlance, the terms are in no way equivalent. For example, one could suggest that the New York Yankees have a "reasonable expectation" of winning the World Series this year, but it would be quite a stretch to contend that this result is "obvious" or "perfectly plain." Only the most ardent Yankees fan would argue otherwise.

Similarly, in describing the factual detail a complaint must allege to survive a Rule 12(b)(6) motion, this Court has stated that the allegations need not satisfy a "probability requirement," but need only provide "enough fact[s] to raise a *reasonable expectation* that discovery will reveal evidence" supporting the claim. *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 556 (2007) (emphasis added). No one reading that statement would think the plaintiff must show that it is "obvious" or "perfectly plain" that discovery will produce supporting evidence. Likewise, this Court has said that a defendant's voluntary cessation of wrongful conduct does not

render a case moot so long as there is a "reasonable expectation that the wrong will be repeated." *City of Erie* v. *Pap's A.M.*, 529 U.S. 277, 287-89 (2000) (internal quotation marks omitted). That standard does not require the defendant's future wrongdoing to be "obvious." *Id.* (case involving nude dancing establishment not moot even though owner had shut the business and sold the property).

So, too, an inventor may have a "reasonable expectation" that an approach will solve the problem at hand, even though success cannot be anticipated without actual experimentation. But that does not mean the inventor can "plainly foreshadow[]" or "predict[]" the success beforehand or that the success is obvious in a way that deprives the owner of the patent rights Congress intended to confer.

Barr points out that the Federal Circuit cited *KSR* before redefining "predictability" and falling back on the Circuit's decades-old "reasonable expectation" standard. Opp. 15-16; see Pet. App. 9a-10a, 15a. But this is precisely the argument the respondent made in *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006), yet this Court granted certiorari and reversed because it was clear that the Federal Circuit, while purporting to follow this Court's precedents, in fact had adopted a crabbed interpretation at odds with the statute and this Court's decisions. Merely citing this Court's decisions is not enough. The lower courts must actually follow them.

3. Certiorari is especially warranted because the erroneous "reasonable expectation" standard is firmly entrenched in Federal Circuit obvious-to-try jurisprudence. See Pet. 20-22. Barr tries to brush off the many examples of these decisions by claiming that the cases were "fact-intensive." Opp. 21-23. But fact-intensive or not, the point remains that every

one of those decisions expressly applied a legal standard that conflicts with § 103 and this Court's guidance. None suggested that the outcome would be the same under this Court's test.

Moreover, Barr is incorrect in claiming that the Federal Circuit's problematic cases were all decided before *KSR*. Opp. 21. In addition to *Pharmastem Therapeutics, Inc.* v. *Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007), which the petition cites, Pet. 21, numerous other post-*KSR* cases have construed § 103 to require no more than a "reasonable expectation of success." *E.g.*, *Amgen*, 580 F.3d at 1362 (citing Federal Circuit precedent in stating that "[a]n obviousness determination requires that a skilled artisan would have perceived a reasonable expectation of success in making the invention in light of the prior art"); *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (invoking the Federal Circuit's "longstanding case law" which asks whether there was "'reasonable expectation of success'"). In any event, the Federal Circuit's pre-*KSR* cases are entirely relevant because *KSR* did not alter the § 103 standard, but instead repeatedly grounded its analysis in the Court's "earlier precedents." 550 U.S. at 422. Federal Circuit decisions finding obviousness based upon "reasonable expectations" and "viable options" were wrong before *KSR* and they are still wrong today, even as they persist as the law of the Circuit. *E.g.*, *Verlander* v. *Garner*, 348 F.3d 1359, 1377 (Fed. Cir. 2003) (applying "viable option" standard).

4. That some panels in the Federal Circuit have applied the correct standard only bolsters the case for certiorari. See Pet. 21-22. Barr does not dispute that internal inconsistency within the Federal Circuit on matters of patent law is a compelling basis for this Court's review. Instead, Barr tries to dismiss the

conflicting decisions as reflecting factual differences. Opp. 23-24. But, that wishful thinking is contradicted by the public disagreement among Federal Circuit judges over the § 103 standard. *E.g.*, *Pfizer, Inc.* v. *Apotex, Inc.*, 488 F.3d 1377 (Fed. Cir. 2007) (Newman, Lourie, & Rader, JJ., dissenting from denial of petition for rehearing en banc); see Pet. 21-22.

Barr accuses Bayer of contrasting cases in which the patentee won or lost in order to conjure this intra-circuit split. Opp. 23-24. This is misleading, as Bayer takes issue with the standards applied in those cases, not their results. There are Federal Circuit decisions that apply the correct "predictability" standard and yet invalidate a patent. *E.g.*, *Ecolab, Inc.* v. *FMC Corp.*, 569 F.3d 1335, 1350 (Fed. Cir. 2009) (without invoking the "reasonable expectation" standard, overturning a jury finding of nonobviousness because the claimed invention was "merely the combination of familiar elements to yield predictable results"). And there are Federal Circuit decisions that apply the incorrect "reasonable expectation" standard but nonetheless find the patent nonobvious. *E.g.*, *Amgen*, 580 F.3d at 1363 (applying only the "reasonable expectation" standard, and yet affirming nonobviousness of patent because the person of ordinary skill would have faced "'great uncertainty'" regarding the claimed invention). Regardless of whether the patentee wins or loses in any given case, the Federal Circuit's *legal standard* in the majority of these cases is irreconcilable with this Court's precedents.

5. Barr is also mistaken in disregarding the deep split between the Federal Circuit and all other circuits to have addressed the question presented. See Pet. 22-25. To be sure, the regional circuit's

decisions pre-dated *KSR*, and many (but not all, contrary to Barr's representation, Opp. 25) of those decisions pre-dated the creation of the Federal Circuit in 1982. But *KSR* did not change this Court's case law, which had long featured terms like "plainly indicated" and "perfectly plain." See *supra* 1-2. And, as noted, Congress codified the term "obvious" in 1952. Thus, regional circuits applied § 103 and this Court's preexisting cases for 30 years before the Federal Circuit's creation. It is therefore quite telling that no court of appeals has ever employed the Federal Circuit's erroneous standard.

II. BARR'S ARGUMENTS AGAINST CERTIORARI LACK MERIT.

Well aware that the decision below cannot be reconciled with this Court's precedents or the decisions of other circuits, Barr attempts to manufacture reasons to deny review. None has merit.

1. First, Barr contends that the petition "depends on factual assumptions" and "effectively takes issue with the lower court's reading of the facts." Opp. 7. This is false. The facts discussed by Barr are completely irrelevant to the question presented, which seeks review only of the panel majority's erroneous legal standard.

Moreover, neither lower court remotely suggested that Bayer would lose under the correct § 103 test of predictability. To the contrary, the district court found only that micronization amounted to a "viable option," Pet. App. 72a, and that a formulator "would not [have] rule[d] out" developing uncoated, micronized drospirenone, *id.* at 76a, even though its success "require[ed] verification through precise" laboratory and clinical testing, *id.* at 89a. Given

those factual findings, the panel majority based its obviousness holding on its view that Bayer's claimed invention was a "viable known option to consider" with a "reasonable expectation" of "perform[ing] similarly (even if not identically)" to a related compound. *Id.* at 14a. The majority recognized that both options had "drawbacks," *id.* at 13a, and the inventor was at a "crossroads," *id.* at 15a. Nonetheless, despite the need for actual and rigorous experimentation, the results of which could not have been anticipated, the majority found the invention to be obvious.

Simply put, the panel majority's precise legal test mattered to the proper resolution of this case. This petition seeks review of that test. The issue is cleanly presented. And certiorari is needed to bring the Federal Circuit in line with 150 years of this Court's precedent and Congress's intent.

In any event, it is worth noting that Barr's selective recounting of the facts mischaracterizes the record and the decisions below. First, no prior art taught that micronized, uncoated drospirenone would be 99% effective, and neither lower court so held. Although some prior art taught using drospirenone as an oral contraceptive, Pet. App. 92a-93a, none established the drug had the requisite efficacy when micronized and delivered in an uncoated pill. Second, no prior art post-dated the clinical trial in the United States that the district court found was "necessary to determine effectiveness." *Id.* at 112a; see also *id.* 42a (clinical study ended on July 16, 1998); *id.* at 40a, 41a, 79a nn.21-22, 92a nn.30-31 (dates of prior art). Third, the panel majority did not even purport to rely on the "five pieces of prior art," Opp. 3. It cited only Krause and only to establish that micronized, uncoated drospirenone "*may* absorb" properly, was a

"viable known option *to consider*," and had a "reasonable expectation" of performing similarly to another drug. Pet. App. 14a (emphases added).

Thus, as the Federal Circuit recognized, the inventor skilled in the art was truly at a "crossroads" in light of the prevailing scientific uncertainty. Complete failure remained a possibility. Clinical trials were necessary, and the invention was far from obvious. Barr's attempt to bolster the decision below by manipulating the record reveals just how wrong the holding under review is and why certiorari in this case is particularly warranted.

2. Barr next contends that review is unwarranted because the majority's "viable options" language was a mere "passing reference" that should be disregarded in light of its "context," Opp. 17-18. This is pure fantasy. The court's "viable option" finding was a cornerstone of its analysis, repeated throughout the majority opinion, see Pet. App. 12a ("viable option"); *id.* ("viable option"); *id.* at 14a ("viable known option"); *id.* at 15a ("known options"), and in other Federal Circuit decisions, *e.g.*, *Verlander*, 348 F.3d at 1377.

Further, even setting aside the "viable option" language entirely, the panel majority's opinion remains fundamentally at odds with this Court's precedents. Barr does not dispute that the Federal Circuit applied a "reasonable expectation" test. And, as explained above, having a "reasonable expectation" of success does not mean the eventual success is "obvious," "perfectly plain," or "predictable."

3. Finally, Barr tries to create a vehicle problem where none exists by claiming that Bayer "urged" adoption of the "reasonable expectation" standard below. Opp. 17 (emphasis omitted). Bayer made no

such argument. Instead, recognizing that the Federal Circuit had already adopted the "reasonable expectations" test and repeatedly applied it over the course of nearly three decades, Bayer argued that the Federal Circuit should construe it in a manner consistent with this Court's predictability standard. *E.g.*, Bayer Opening Br. 32-33 (July 9, 2008); Bayer Combined Pet. for Panel Reh'g & Reh'g En Banc 4-5 (Sept. 4, 2009). The Federal Circuit declined to do so and instead followed its own pre-*KSR* precedent, holding an invention to be obvious-to-try even though the person of ordinary skill would have reached a "crossroads," having mere "viable options" to consider, both of which might have failed, and both of which required actual experimentation. Pet. App. 12a-15a. Thus, the question presented was both "'pressed'" and "'passed upon'" below, leaving no barrier to this Court's review. *United States* v. *Williams*, 504 U.S. 36, 41 (1992).[1]

III. THE QUESTION PRESENTED HAS ENORMOUS CONSEQUENCES FOR A BROAD RANGE OF INDUSTRIES.

Barr makes little effort to downplay the implications of this case. For good reason: the proper § 103 standard affects all existing patents, which are subject to challenge in courts and reexamination by the Patent and Trademark Office ("PTO"), as well as all future patent applications. In its guidelines, the

---

[1] The licensing agreement that Barr mentions in a footnote is a complete non-issue (Opp. 7 n.3), as Barr itself argued in the Federal Circuit. Because the agreement includes a differential royalty rate, under which Barr pays more money if it loses the case, federal jurisdiction unquestionably remains. *See Nixon* v. *Fitzgerald*, 457 U.S. 731, 743-44 (1982). The panel did not even address the issue, raised only by an amicus, because the issue is so insubstantial.

PTO has expressly directed its patent examiners to follow the Federal Circuit's incorrect standard. See Pet. 25-27.

This serious problem will not be resolved, as Barr suggests, by allowing the PTO to revise its guidelines after "reviewing court decisions." Opp. 28 (quoting David Kappos, Director, U.S. Patent and Trademark Office, *The Impact of* KSR (Nov. 24, 2009), www.uspto.gov/blog/). Unless this Court grants certiorari, the court decisions that the PTO would review would primarily, if not exclusively, be Federal Circuit decisions. There is no reason to think that the PTO can or will correct its guidelines by studying the Federal Circuit's incorrect case law. And, even if the PTO did reform its guidelines, there is no reason to expect that the Federal Circuit, which gives no deference to the PTO's legal conclusions regarding obviousness, would follow suit. *E.g.*, *Kubin*, 561 F.3d at 1355.

To be sure, the Federal Circuit's overly lax "reasonable expectation" standard is not new. Before *KSR*, however, its harmful consequences were blunted by the Federal Circuit's overly stringent teaching-suggestion-motivation test. See Pet. 29-30. Since *KSR*, the Federal Circuit has applied the "reasonable expectation" standard as a stand-alone obviousness test. The effect is to remove patent protections Congress intended to provide, to cast a shadow over many existing patents, and to deter firms from undertaking the resource-intensive research that drives innovation. See *id.* at 27-28 (explaining that, on average, a new drug costs between $800 million and $1.2 billion to develop and bring to market, and takes 12 years to complete). This Court's intervention is urgently needed.

CONCLUSION

For these reasons, and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

PETER B. BENSINGER, JR.
ADAM K. MORTARA
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 W. Hubbard Street
Suite 300
Chicago, IL 60654
(312) 494-4400

CARTER G. PHILLIPS*
JEFFREY P. KUSHAN
JONATHAN F. COHN
MATTHEW D. KRUEGER
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
cphillips@sidley.com

Counsel for Petitioners

* Counsel of Record

April 13, 2010